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Bionpharma, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**COMPLAINT**
	)	
CORERX, INC.,	)	
	)	
Defendant.	)	
	)	

Plaintiff Bionpharma Inc. ("Bionpharma"), by way of complaint against defendant CoreRx, Inc. ("CoreRx"), alleges and says:

THE PARTIES

1. Plaintiff Bionpharma is a Delaware corporation with its principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, New Jersey.

2. Defendant CoreRx is a Florida corporation with its principal place of business at 14205 Myerlake Circle, Clearwater, Florida.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) and 28 U.S.C. § 2201(a). Complete diversity of citizenship exists because this action involves a

dispute between citizens of different states and the amount in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.

4. This Court has personal jurisdiction over CoreRx at least because CoreRx consented to jurisdiction in this Court (Exhibit A, Section 16.8).

5. Venue is proper based in this district at least because CoreRx consented to venue in this Court (Exhibit A, Section 16.8).

BACKGROUND

6. In November 2020, Bionpharma and CoreRx entered into that certain Master Manufacturing Supply Agreement (the "Agreement") concerning in part terms under which (i) CoreRx is to supply Bionpharma's requirements of enalapril solution (the "Product") generic to the branded product Epaned, and (ii) Bionpharma is to purchase its requirements of the Product from CoreRx (Exhibit A, Section 5.1). A copy of the Agreement, with financial terms and nonpublic information concerning the Product omitted, is annexed hereto as Exhibit A.

7. The purpose of the Agreement is for Bionpharma to acquire Product for resale in the wholesale market for generic pharmaceuticals.

8. Bionpharma holds approved Abbreviated New Drug Application ("ANDA") A212408 for the Product, and commenced selling the Product pursuant to that approval on or about August 17, 2021.

9. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iv), no other ANDA based on Epaned as the reference listed drug may be approved prior to February 13, 2022. Accordingly, at least until that date, Bionpharma enjoys a period during which the Product is the only approved generic to Epaned in the United States.

10. In order to obtain approval of its ANDA for the Product and maintain freedom to

sell the Product, Bionpharma expended and continues to expend significant resources to defeat claims for patent infringement filed against it by Azurity Pharmaceuticals, Inc. ("Azurity"), which holds the marketing authorization for Epaned, and Azurity's predecessor Silvergate Pharmaceuticals, Inc. ("Silvergate").

11. In December 2018, Silvergate (subsequently Azurity) sued Bionpharma in the U.S. District Court for the District of Delaware for infringement of several patents on account of Bionpharma's submission of an ANDA seeking approval to sell the Product. That case went to trial, and on April 27, 2021, the district court ruled that the Product did not infringe the remaining asserted patents. *Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A., No. 18-1962-LPS (D. Del.), ECF No. 257, Apr. 27, 2021 Op.; *Silvergate Pharms. Inc. v. Bionpharma Inc.*, C.A. No. 19-1067-LPS (D. Del.), ECF No. 244, Apr. 27, 2021 Op.; *Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. CV 18-1962-LPS 2021, WL 1751148 (D. Del., April 29, 2021) (redacted public version of Apr. 27, 2021 Op. in C.A. Nos. 18-1962-LPS and 19-1067-LPS (D. Del.) ("First Wave Suits")). On April 29, 2021, the district court entered final judgment in Bionpharma's favoring the First Wave Suits. *Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A., No. 18-1962-LPS (D. Del.), ECF No. 270, Final J.; *Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A., No. 19-1067-LPS (D. Del.), ECF No. 257, Final J. A related action that Azurity filed against Bionpharma on September 18, 2020 involving later-issued patents in the same family—*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-LPS (D. Del.) ("Second Wave Suit")—was dismissed with prejudice absent a ruling on appeal of the First Wave Suits eliminating collateral estoppel.

12. Having lost the First and Second Wave Suits in Delaware, Azurity decided to try its luck in a different jurisdiction, and filed a new case in June 2021 against Bionpharma in the

U.S. District Court for the District of New Jersey, alleging that sale of the Product would infringe yet another patent. Azurity sought a preliminary injunction, which Bionpharma opposed. Recognizing Azurity's forum shopping, the District of New Jersey granted Bionpharma's motion to transfer the case to the District of Delaware. After the case was transferred, the District of Delaware denied Azurity's motion for a preliminary injunction on November 10, 2021, finding, *inter alia*, that Azurity had not shown a likelihood of success on the merits. *Azurity Pharms., Inc. v. Bionpharma Inc.*, No. 21-cv-01286-LPS (D. Del.), ECF No. 87, Nov. 10, 2021 Oral Order. On October 15, 2021, Azurity filed yet another suit against Bionpharma involving yet another continuation patent. *Azurity Pharms., Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.). Both C.A. Nos. 21-1286-LPS and 21-1455-LPS (D. Del.) ("Third Wave Suits") remain pending.

13. Not content to litigate only against Bionpharma, Azurity in October 2021 also filed two substantially identical suits against CoreRx, alleging that CoreRx's actions in manufacturing the Product for Bionpharma infringed two patents that Azurity was already asserting against Bionpharma in connection with the Third Wave Suits. *Azurity Pharms., Inc. v. CoreRx, Inc.*, 1:21-cv-01522 (D. Del.); *Azurity Pharms., Inc. v. CoreRx, Inc.*, 8:21-cv-02515 (M.D. Fla.).

14. On or about November 26 and 29, 2021, Azurity voluntarily dismissed both of its suits against CoreRx. ECF No. 6, *Azurity Pharms., Inc. v. CoreRx, Inc.*, 1:21-cv-01522 (D. Del.); ECF No. 16, *Azurity Pharms., Inc. v. CoreRx, Inc.*, 8:21-cv-02515 (M.D. Fla.).

15. By virtue of the dismissals of the two cases filed against it by Azurity, CoreRx cannot have a reasonable apprehension that it might face liability to Azurity on account of purported patent infringement arising from CoreRx manufacturing the Product for Bionpharma. FED. R. CIV. P. 41(a)(1)(B).

16. Further, the terms of the Agreement generally provide for indemnification by Bionpharma of CoreRx for claims for patent infringement arising from CoreRx's manufacture of the Product for Bionpharma. (Exhibit A Sections 13.1 and 13.3).

17. On November 30, 2021, CoreRx sent a fax to Bionpharma stating "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for" the Product. A copy of that notice is annexed hereto as Exhibit B.

18. In response to that fax, Bionpharma requested that CoreRx advise Bionpharma why CoreRx was not able to supply the Product, demanded that CoreRx continue to supply the Product, and gave notice of CoreRx's breach of the Agreement. A copy of Bionpharma's correspondence to CoreRx is annexed hereto as Exhibit C.

19. On or about August 26, 2021, Bionpharma had placed an order with CoreRx for a quantity of Product in accordance with the forecasts provided to CoreRx. A copy of the order, with financial terms and nonpublic information concerning the Product omitted, is annexed hereto as Exhibit D.

20. The order referred to in paragraph 19 above is a Firm Order pursuant to the Agreement (Exhibit A Section 5.3), and complies with all contractual formalities and requirements.

21. CoreRx has manufactured and Bionpharma has taken possession of approximately 30% of the ordered Product from the order referred to in paragraph 19. The balance remains outstanding. These bottles of Product had been scheduled to be shipped by CoreRx to Bionpharma on December 28, 2021.

22. In addition to the correspondence in Exhibit B, CoreRx has advised Bionpharma that it will not manufacture and ship to Bionpharma the remaining approximately bottles of

Product that are the subject of the Firm Order.

23. Upon information and belief, based on the following, CoreRx procured its purported inability to supply Product to Bionpharma through an agreement with Azurity, which is now a sister company of CoreRx under private equity control:

a. In or around January 2021, CoreRx was purchased by Novaquest Investment Management or an affiliate ("Novaquest").

b. Novaquest also owns Azurity.

c. Of the seven members of the board of directors of CoreRx, five are also on the board of directors of Azurity (the "Overlapping Directors"), and several also have positions at Novaquest:

1. Frank Leo – board member of CoreRx; chairman of the board of Azurity.

2. Nailesh Bhatt – board member of CoreRx; board member of Azurity.

3. Jeff Edwards – board member of CoreRx; board member of Azurity; founder and investment committee member of Novaquest.

4. Ashton Poole – board member of CoreRx; board member of Azurity; partner at Novaquest.

5. Vern Davenport – board member of CoreRx; board member of Azurity; partner and member of the private equity investment committee at Novaquest.

d. The five Overlapping Directors named above also constitute a majority of the seven-member board of Azurity.

e. In addition to the Overlapping Directors, Ajay Damani, who became CEO and a board member of CoreRx in October 2021, was immediately prior to that a Strategic Advisor with Novaquest.

f. The fax from CoreRx to Bionpharma stating that CoreRx would no longer supply Product to Bionpharma was sent on November 30, 2021, *i.e.*, one day after the dismissal of the second suit against CoreRx by Azurity, which was filed on November 26, 2021, suggesting a connection between dismissal of Azurity's complaints against CoreRx and CoreRx's refusal to continue supplying Bionpharma.

g. On December 7, 2021, Azurity filed a letter in one of the Third Wave Suits against Bionpharma (21-1286-LPS (D. Del.)) stating that "Azurity's dismissals against CoreRx Inc., Bionpharma's manufacturer, were resolved and dismissed by mutual agreement." A copy of the letter is annexed hereto as Exhibit E.

h. The cessation of generic competition for Epaned resulting from CoreRx's refusal to supply Product to Bionpharma directly benefits Azurity, which is related to CoreRx through Novaquest.

i. Other than seeking to benefit its related company Azurity, there is no apparent economic or business reason for CoreRx to discontinue supply of Product to Bionpharma under the Agreement.

j. On or about November 19, 2021, CoreRx complained to Bionpharma that the price it had negotiated for supply of Product in the Agreement was too low, and that it wanted Bionpharma to agree to a substantial price increase, even

though the price in the Agreement had been negotiated just one year ago, and even though the costs of materials and manufacturing had not substantially increased between the time the Agreement was entered into in November 2020 and CoreRx's demand for a price increase in November 2021.

k. CoreRx has refused to tell Bionpharma the reason why it is purportedly unable to continue supply of Product to Bionpharma under the Agreement.

l. CoreRx has not experienced a Force Majeure Event under the Agreement (Exhibit A Section 16.9).

COUNT 1 – BREACH OF CONTRACT

24. Bionpharma incorporates all prior allegations as if set forth fully herein.

25. Bionpharma has performed its obligations under the Agreement.

26. By refusing to supply Product to Bionpharma under the terms set forth in the Agreement, CoreRx has breached and is in breach of the Agreement.

27. Bionpharma will suffer damages on account of CoreRx's breach of the Agreement.

28. Manufacture and sale of the Product is subject to and regulated under the federal Food, Drug & Cosmetic Act, and implementing regulations adopted by the U.S. Food & Administration.

29. Given that CoreRx gave Bionpharma only one day notice that CoreRx would not continue to supply Product under the Agreement, Bionpharma cannot secure an alternate supplier of Product before it exhausts the inventory of Product it has on hand.

30. If CoreRx does not continue to supply Product under the Agreement until Bionpharma is able to secure an alternate supplier, Bionpharma will suffer irreparable injury.

COUNT 2 – DECLARATORY JUDGMENT

31. Bionpharma incorporates all prior allegations as if set forth fully herein.

32. By virtue of the foregoing, there is an actual and present controversy between Bionpharma and CoreRx that is amenable to resolution by declaratory judgment.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Bionpharma demands judgment against defendant CoreRx as follows:

A. For injunctive relief compelling CoreRx to continue to supply Product for the duration of the Agreement under the terms thereof, or at least until Bionpharma is able to arrange for, and secure sufficient quantities of Product from an alternate supplier.

B. Declaring that CoreRx is in breach of the Agreement, and that it is required to continue to supply Product for the duration of the Agreement under the terms thereof.

C. Awarding Bionpharma its actual damages.

D. Awarding costs of suit and reasonable attorneys' fees.

E. Awarding such other and further relief as may be appropriate.

DATED: December 13, 2021

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